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October 23, 2019

VIA ELECTRONIC MAIL
Honorable Freda L. Wolfson, Chief Judge
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Re: ***In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation (MDL No. 2738)***

Dear Chief Judge Wolfson:

The PSC writes to address several inaccurate statements made by the Johnson & Johnson Defendants ("J&J" or "Defendants") in their October 22, 2019 letter regarding the recall of Johnson's Baby Powder that tested positive for asbestos.

As an initial matter, the FDA commissioned testing of two samples of Johnson's Baby Powder: one sample from lot # 22318RB tested positive for asbestos; a second sample from lot # 00918RA tested negative for asbestos.[1] The negative results undercut J&J's baseless assertion of cross-contamination. As to J&J's other inaccuracies, the PSC responds as follows:

First, J&J contends that the presence of asbestos in Johnson's Baby Powder does not "move the needle" on any issue relating to general causation because the presence or absence of known carcinogens, like asbestos, cannot explain the epidemiologic aspects of Bradford Hill (e.g., strength of association, consistency, dose response, etc.). However, J&J's letter completely

[1] U.S. Food and Drug Administration, Oct. 18, 2019 Update - FDA Advises Consumers to Stop Using Certain Cosmetic Products, available at www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products (last visited Oct. 23, 2019).

ignores Bradford Hill's non-epidemiological factor: biological plausibility. The fact that J&J's talcum powder products have been shown by multiple labs – including the FDA's – to contain asbestos, further reinforces that it is biologically plausible that the consistent association between talcum powder products and ovarian cancer in the epidemiological studies is indeed a causal association. Moreover, J&J's characterization that the amount found by the FDA is "trace" is misleading. J&J's position is, and always has been, that its talcum powder products do not contain asbestos. Additionally, the amount of asbestos contained in a single bottle, let alone a single microscopic sample from within a single bottle, is not the measure of a woman's total exposure, as women typically use powder routinely for years and are exposed to numerous bottles over the course of their lives. A bottle containing 0.00002% chrysotile, like the one tested by the FDA, would contain millions of fibers of chrysotile.

Second, J&J misstates the FDA's prior efforts and findings regarding its testing of talcum powder products. In 2009, because of ongoing safety concerns about the presence of asbestos in talc, the FDA commissioned independent testing of currently marketed cosmetic-grade raw talc, as well as some in-market cosmetic products containing talc. Because the FDA's cosmetic laboratories are not equipped to test talc, the FDA contracted AMA Analytical Services, Inc. ("AMA") to conduct a study analysis over a year period. The study results were "limited" because only four of nine talc suppliers complied with the FDA's request for samples and only thirty-four cosmetic products containing talc, including J&J's Johnson's Baby Powder and Shower to Shower, were available for analysis. Although the survey testing was unable to detect asbestos fibers or structures in the limited samples provided, the FDA heavily qualified its conclusions, noting "…while FDA finds these results informative, they do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination."[2]

Third, J&J claims that chrysotile has not been associated with the Chinese mine used to source its products. Since 2003, the talc in J&J's talcum powder products has been mined from the Jizhua mine, which is located in the Guangxi province and owned by the Chinese government.[3] To date, J&J has not produced any geologic data regarding the Jizhua mine, such as core logs or detailed maps of the ore deposit. Any suggestion by J&J that there is a comprehensive understanding of the geology of the Chinese mine, and that chrysotile is not present in this mine, is unsupported by the evidence.

Contrary to J&J's claim, chrysotile has been previously identified in talc mined from this mine. In 2010, Imerys Technical Director Ed McCarthy reported the presence of tremolite and serpentine (chrysotile when fibrous) in Chinese talc ores.[4] Mr. McCarthy further stated that

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[2] U.S. Food and Drug Administration, Talc: FDA's Talc Survey of 2009-2010, available at https://www.fda.gov/cosmetics/cosmetic-ingredients/talc (last visited Oct. 23, 2019).
[3] ECF No. 9892, n. 163.
[4] ECF No. 9892, Exhibit 53.

fibrous minerals cannot be eliminated from the talc ore to meet cosmetic standards. In 2016, chrysotile particles were found in talc sourced from China.[5]

Moreover, J&J erroneously argues that the FDA findings "undermine" Dr. Longo's test results. This is an absurd turnabout to J&J's prior arguments that there has "never" been asbestos in its talc and, therefore, Dr. Longo's testing methodology that found asbestos must have been "wrong." The fact is the FDA confirmed the presence of asbestos in J&J's finished talcum powder products. This confirms Dr. Longo's findings. To only now attempt to differentiate the FDA findings from Dr. Longo's by stating that it is a "different" type of asbestos reveals (1) that J&J's entire motion to exclude – based on the "no asbestos ever" premise – rested on a factual charade; and, (2) that J&J has no rebuttal to the FDA's unequivocal findings that corroborate Dr. Longo's results.

As noted in its October 18, 2019 letter, the PSC is making every effort to obtain documents and data from J&J and the FDA on an expedited basis and requests the opportunity to supplement the record once received. The PSC does not wish to reopen *Daubert* briefing or further delay the Court's consideration of the issues therein.

Respectfully submitted,

/s/ Michelle A. Parfitt
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/s/ P. Leigh O'Dell
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Cc: Susan Sharko, Esq.
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[5] ECF No. 9892, Exhibit 56.